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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,691	09/05/2001	Angus George Dalgleish	37945-0018	6462

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HELLER EHRMAN WHITE & MCAULIFFE LLP
1666 K STREET,NW
SUITE 300
WASHINGTON, DC 20006

EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/857,691	DALGLEISH ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *10 September 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*.

Claim(s) objected to: *none*.

Claim(s) rejected: *1,11,12,25 and 26*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *attached interview summaries*

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1, 11-12, 25-26 are being examined.

The following are the remaining rejections.

OBJECTION

Claims 1, 11-12, 25-26 are objected to for the use of designation "PNT-2, NIH-1542" as the sole means of identifying the claimed cell lines, because different laboratories may use the same laboratory designations to define completely distinct cell lines. Amendment of the claims to include, for example, the ATCC number for each cell line would obviate this rejection.

DEPOSIT REQUIREMENT

The specification is objected to under 35 USC 112, first paragraph, as failing to provide an enabling disclosure and failing to provide an adequate description of the claimed invention without evidence that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

Applicant recites in the response of 09/10/04 Nishimua et al, US 6,699,483, Table 1, and Bright et al, arguing that the cell line NIH-1542 is available from NIH.

The recitation of Nishimua et al, US 6,699,483, Table 1, and Bright et al is acknowledged.

Although cell line NIH-1542-CP3TX was recited in table 1 of US 6,699,483 as having been deposited at ATCC, the cell line 1542-CP3TX, CRL-12037 is not publicly available from ATCC, according to an official representative of ATCC, in a telephonic conversation of 11/05/04 (see attached interview summary).

Applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. Applicant's provision of these assurances would obviate this objection/rejection.

Applicant's attention is directed to 37 CFR 1.801-1.809 for further information concerning deposit practice.

For the reasons set forth above, claims 1, 11-12, 25-26 are rejected under 112, first paragraph.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 1, 11-12, 25-26, because while being enabled for an allogeneic immunogenic agent, the specification is not enabled for an" immunotherapeutic agent", remains for reasons already of record in paper of 03/11/04.

Applicant argues in paper of 06/07/04 that Applicant's phase I human and mouse data submitted in the instant application and the Walker Declaration are sufficient to establish enablement of the claimed cell lines in the treatment of cancer.

This is not found to be persuasive. It is noted there is no data from the reference to Phase I trial, or mouse treatment in the specification, or in the Walker Declaration, showing successful treating of cancer using the claimed cell lines. It is not clear on what basis that Applicant concludes that the claimed cell lines could be used for treating cancer, in view of the overwhelming teaching in the art that cancer treatment is unpredictable (Gura et al, Jain et al, Curti et al, and Hartwell et al, Boon et al, all of record).

Applicant argues that the references by Gura et al, Jain et al, Curti et al, and Hartwell et al are outdated. Applicant argues that the claimed cell lines show the T-cell proliferation responses in patients and that the PSA level decreases in 50% of treated patients. Applicant argues that since Boon et al teach that CTL responses are not always essential for rejection, and depend entirely on the nature of the initial tumor, a lack of T cell response or increase in CTLs would not negate a prediction as prediction whether an immune response is indicative of effective prostate cancer.

Applicant recites Martin et al, arguing that the tumor burden during therapy has little impact upon survival time.

Applicant recites Scher et al, arguing that the PSA level is still widely used and accepted as a tumor marker for prostate cancer.

The recitation of Martin et al, and Scher et al is acknowledged.

Applicant's arguments set forth in paper of 06/07/04 have been considered but are not deemed to be persuasive for the following reasons:

The teaching of Gura et al, Jain et al, Curti et al, and Hartwell et al that cancer treatment is unpredictable is still true to date, especially Applicant has not shown any recent reference refuting the unpredictability of cancer treatment.

Further, since the assertion by Applicant that the claimed cell lines could be used for treating cancer seems to be based on the disclosure in the specification that the cell lines elicit T cell response, it is clear from Boon reference, and as confirmed by Applicant's response, the presence or absence of T cell response alone cannot be predictive of the effectiveness of cancer treatment.

Further, although the PSA level is still widely used and accepted as a tumor marker for prostate cancer, it is noted that Applicant has not disclosed that the conditions in which PSA levels in the patients are used as marker for prostate cancer are the same as those in the instant application, i.e. administrating into patients prostate cancer cell lines that produce PSA, or having PSA on the cell surface, wherein one cannot predict whether such administration could produce anti-PSA antibodies, that complex to PSA and reduce amount of PSA in the serum.

Concerning Applicant's remark that as per Martin et al, the tumor burden during therapy have little impact upon survival time, it is noted that tumor burden is not an issue here, but rather the immune tolerance caused by cancer, which is well known in the art, as taught by Boon et al, that makes treating cancer unpredictable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

January 13, 2005